Remarks

Claims 24-159 and 285-305 are pending. The dependencies of claims 45, 47, 50 and 53-55 have been amended. No new matter has been introduced.

Pursuant to Paper No. 17, mailed August 28, 2001 the Examiner has required an additional election of an amino acid within Group I, as defined by the Examiner in Paper No. 13, mailed December 7, 2000. More particularly, the Examiner has required an election under 35 U.S.C. § 121 of:

> a single invention of an nucleic acid, selected from the group consisting of (i.e. elect one from the following Markush group): a nucleic acid comprising an polynucleotide encoding a protein selected from the group consisting of the following regions of SEQ ID NO:2: Residues 1-300, 2-300, 31-300, 31-283, 49-300, 1-193, 31-46, 57-117, 132-175, 185-194, 205-217, 239-264, 283-298 or a single ultimate species of polynucleotide encoding a fragment o9f SEQ ID NO:2 wherein the fragment is at least ≥ 30 contiguous amino acids or ≥ 50 contiguous amino acids, or nucleotides 92-946 of SEQ ID NO:1, or a nucleic acid molecule encoding one of the following amino acid sequences encoded by the cDNA contained in ATCC deposit 97810, the full-length polypeptide, the full-length polypeptide excluding the amino-terminal methionine, the mature polypeptide, the soluble extracellular polypeptide, the complete amino acid sequence excluding up to 48 amino acid residues from the amino terminus, the complete amino acid sequence excluding up to 107 amino acid residues from the carboxy terminus, the complete amino acid sequence excluding up to 48 amino acid residues from the amino terminus and excluding up to 107 amino acid residues from the carboxy terminus. (See, Paper No. 17, page 3).

Applicants assume the Examiner intended to recite nucleotides 25-924 of SEQ ID NO:1 (recited in claim 30) rather than nucleotide 92-946 of SEQ ID NO:1.

While the Examiner admits that "the classifications for these various nucleic acids are overlapping," the Examiner nevertheless contends that "each represents a patentably distinct product with distinct physical and functional characteristics." *Id* at pages 3-4. The Examiner further contends that:

> the search for more than one product would be burdensome, because most are claimed not by nucleic acid sequence but by the sequence of the protein

> encoded thereby, and requires a search of the corresponding SEQ ID NO:1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO:2, such that each individual sequence requires two sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid sequence, which requires a separate word search of the nucleic acid databases. (See, Paper No. 17, page 4).

In order to be fully responsive, Applicants hereby provisionally elect, with traverse, the subject matter of an nucleic acid molecule comprising a polynucleotide sequence encoding amino acid residues 31 to 300 of SEQ ID NO:2 or encoding an amino acid sequence which is at least 90% identical to SEQ ID NO:2. While all the claims are overlapping in scope, claims particularly corresponding to the provisionally elected sequence include: claims 24(c), 27, 31-39, 40(c), 43, 45-55 (as amended), 56(c), 59, 62-70, 72(c), 75, and 77-87. Applicants reserve the right to file one or more divisional applications directed to non-elected sequences should the additional restriction requirement be made final. Additionally, should the present restriction requirement be made final, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement. As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).
>
> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the amino acid sequences listed by the Examiner represented distinct or independent inventions, restriction remains improper

unless it can be shown that the search and examination of both groups would entail a "serious burden." *See* M.P.E.P. § 803. In the present situation, no such showing has been made. Indeed, the Examiner has admitted that the classifications for the instant nucleic acids are overlapping, so that a search of one claimed nucleic acid would also provide useful information for other claimed nucleic acids. Indeed, Applicants submit that search of the nucleic acid encoding the full-length polypeptide of SEQ ID NO:2, would provide all data necessary to examine each claimed sequence. Accordingly, the search and examination of the instant nucleic acid sequences would not entail a serious burden.

Moreover, Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for requiring the election of an individual amino acid sequence within the previously elected Group I. Assuming *arguendo* that the Examiner is requiring an election of the members of the Markush-type claims, Applicants respectfully point out that MPEP § 803.02 requires that "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits." Applicants submit that the members of the Markush groups of the pending claims are sufficiently few in number and very closely related, as they are all portions of the same nucleotide sequence, so that a search of all of the members may be made without a serious burden, contrary to the Examiner's position. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that "[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability." If no prior art is found "that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended." *Id.* (emphasis added).

Further, Applicants point out that the Examiner has not addressed MPEP § 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), §803.04 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Applicants submit that the instant nucleotide sequences constitute different fragments of the same nucleotide sequence, rather than different nucleotide sequences as contemplated by § 803.04. "[S]equences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." *Id.* Thus, Applicants respectfully submit that the present requirement for election is improper.

Accordingly, in view of the foregoing, all of the claims of previously elected Group I should be searched and examined in the present application. Applicants therefore respectfully request that the additional requirement for an election of an amino acid sequence within the previously elected Group I be reconsidered and withdrawn, and that the instant claims be examined in one application.

Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension

of time under 37 C.F.R. § 1.136 not accounted for in the Petition for an Extension of Time submitted concurrently herewith, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: SEPTEMBER 28, 2001

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Enclosures

HAND DELIVERY SEPTEMBER 28, 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Gentz et al.

Art Unit: 1646

Application Serial No.: 09/006,352

Examiner: O'Hara, E.

Filed: January 13, 1998

Attorney Docket No.: PF454

Title: Tumor Necrosis factor 6α and 6β

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amendments are shown in bold with insertions indicated with underlining and deletions indicated by strikeout.

45. (Once Amended) The nucleic acid molecule of claim **43** ~~44~~ encoding a first amino acid sequence at least 95% identical to a second amino acid sequence according to **(c)** ~~(d)~~.

47. (Once Amended) The nucleic acid molecule of claim **45** ~~44~~ that comprises a nucleotide sequence heterologous to SEQ ID NO:1.

50. (Once Amended) A recombinant vector comprising the nucleic acid molecule of claim **45** ~~44~~.

53. (Once Amended) A recombinant host cell comprising the nucleic acid molecule of claim **45** ~~44~~ operably associated with a regulatory element that controls expression of said nucleic acid molecule.

54. (Once Amended) A method of producing a polypeptide encoded by the nucleic acid molecule of claim **45** ~~44~~ comprising:

(a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and

(b) recovering said polypeptide from the culture.

55. (Once Amended) A composition comprising the nucleic acid molecule of claim **45** ~~44~~ and a pharmaceutically acceptable carrier.